

**AIR FORCE MATERIEL COMMAND
AIR FORCE RESEARCH LABORATORY**

**ADVANCED AIRCREW OXYGEN
MASK INSERT EVALUATION**

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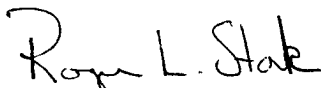
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13. ABSTRACT (Maximum 200 words) The Crew Technology Division of Armstrong Laboratory is developing an insert for the MBU-20/P aircrew oxygen mask. The insert is placed inside the mask to enhance comfort and seal at high mask cavity pressures. The Air Force Operational Test and Evaluation Center, Rapid Test and Evaluation Directorate (AFOTEC/TA), conducted this evaluation of prototype mask inserts using Air National Guard pilots flying training sortics in F-16 aircraft. The evaluation addresses the operational use of an aircrew oxygen mask insert. The objective was to evaluate mask comfort and mask seal. A re-evaluation questionnaire was designed to assess the comfort and seal of the masks without the insert. A post-evaluation questionnaire addressed the comfort and seal of the mask with the insert. It was planned that each pilot would fly with the insert for at least two sortics. Each pilot had their original mask without insert and an unmodified mask with insert so they could swap masks between sortics and evaluate the seal and comfort of the altered mask. Pilots answered questionnaires as soon as possible after the last flights. Eighteen pilots evaluated the insert. Five pilots reported previous seal problems. All five pilots indicated the insert improved the mask seal and they would continue using the insert. However, most pilots indicated there was a problem with the comfort of the mask with the insert. There was an insufficient sample size to make a statistical determination of the mask insert improvement. Seven of 18 pilots stated they would continue to use the mask insert as it improved the mask seal. However, these pilots were split on the issue of improved comfort, and half reported that comfort decreased with the insert.				
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The Crew Technology Division of Armstrong Laboratory is developing an insert for the MBU-20/P aircrew oxygen mask. The insert is placed inside the mask to enhance comfort and seal at high mask cavity pressures. The Air Force Operational Test and Evaluation Center, Rapid Test and Evaluation Directorate (AFOTEC/TA), conducted this evaluation of prototype mask inserts using Air National Guard pilots flying training sorties in F-16 aircraft.

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The evaluation addresses the *operational use* of an aircrew oxygen mask insert. The objective was to evaluate *mask comfort* and *mask seal*. A pre-evaluation questionnaire was designed to assess the comfort and seal of the masks *without* the insert. A post-evaluation questionnaire addressed the comfort and seal of the mask with the insert.

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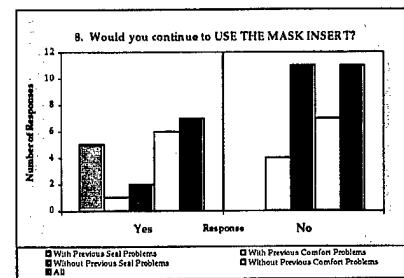
It was planned that each pilot would fly with the insert for at least two sorties. Each pilot had their original mask without insert and an unmodified mask with insert so they could swap masks between sorties and evaluate the seal and comfort of the altered mask. Pilots answered questionnaires as soon as possible after the test flights.

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There was an insufficient sample size to make a statistical determination of the mask insert improvement. Seven of 18 pilots stated they would continue to use the mask insert as it improved the mask seal. However, these pilots were split on the issue of improved comfort, and half reported that comfort decreased with the insert. More testing is needed with a larger sample size to make a statistical determination regarding the benefits of the mask insert.



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1.0 Introduction

1.1 Background

The Crew Technology Division of Armstrong Laboratory (ALCFT) is developing an insert for the MBU-20/P aircrew oxygen mask. The program, known as the Advanced Aircrew Oxygen Mask (AAOM), has as an objective to enhance the comfort and/or seal of the silicone rubber face piece for the MBU-20/P oxygen mask, shown in Figure 1-1. Initial testing concluded that "the mask insert appears to improve the ability to seal the mask efficiently, but there is insufficient evidence to conclude that it improves comfort."¹ It is estimated that 40 percent of pilots have comfort or seal problems with the current oxygen mask. The Air Force Operational Test and Evaluation Center, Rapid Test and Assessment Directorate (AFOTEC/TA), formerly the Defense Evaluation Support Activity (DESA), was asked by ALCFT to plan and conduct an evaluation of a prototype mask insert designed to meet the program objectives.

ALCFT provided 40 prototype inserts to AFOTEC/TA in March 1997 for the evaluation. The field evaluation was conducted using Air National Guard (ANG) pilots assigned to the following Fighter Wings:

- Kirtland Air Force Base (AFB), New Mexico ANG, 150th Fighter Wing
- Fort Smith, Arkansas, Arkansas ANG, 188th Fighter Wing
- Buckley Field, Colorado, 140th Wing
- Montgomery, Alabama ANG, 187th Fighter Wing
- United Kingdom Air National Guard (UKANG), one pilot.



Figure 1-1. MBU-20/P oxygen mask

1.2 Mask Insert Description

The insert, shown in Figure 1-2, is constructed of a Kydex™ frame which supports a urethane rim that bolsters the face piece reflective seal. The insert is placed into the mask and is designed to enhance comfort and/or seal at high mask cavity pressures and high gravity forces (G-forces) by ensuring the mask seal lays flat against the user's face. The frame of the insert is designed with two strips of Kydex™ that cross the mask's valsalva ports, allowing the user to collapse the insert over the nose to facilitate closing off the nasal passages when performing a valsalva maneuver. Other benefits may include improved acoustics within the mask cavity and decreased mask cavity dead space. Since the insert is inexpensive and not permanently fixed to the mask, it can be used on an "as needed" basis and periodically replaced as necessary.

¹ Diesel, Donald A., Major, USAF, BSC, 1997. A Conformal Foam Insert to Improve Comfort and Function of the MBU-20/P Positive Pressure Breathing Oxygen Mask. *SAFE Journal*, Vol. 27, No. 2. p. 104-108.



Figure 1-2. Insert for MBU-20/P oxygen mask

1.3 Scope of Evaluation

This evaluation addressed the *operational use* of an aircrew oxygen mask insert. The seal and comfort of the mask with the insert was evaluated via subjective questionnaires administered to pilot users. Pilots were solicited on a voluntary basis. The target pilot population was those who had either seal or comfort problems with the MBU-20/P oxygen mask, and therefore could benefit from the insert. This document reports the findings from the evaluation.

1.4 Constraints and Limitations

The evaluation was resource constrained (time and funding). AFOTEC/TA attempted to maximize data collection and minimize expenditures by using electronic data collection methods and telephone interviews whenever possible. While this approach helped to conserve scarce resources, it was a constraint on the amount of data collected.

To determine the appropriate sample size, AFOTEC/TA analysts used assumptions concerning the population of potential insert users, and identified an appropriate sampling error and confidence level. Based on this, a sample size of 57 volunteers was required to respond to the program objectives. However, there were only 40 inserts available for testing, and even fewer pilots participating. The final count of volunteers was 18, and was not sufficient for a statistically significant conclusion. However, the discrete results from the 18 pilots were included in this evaluation.

Results could vary between guard units as each life support shop fit the mask with the insert for their pilots. The fit of the mask affects the results of the evaluation, and life support shops may use slightly different techniques. Another fit problem that may have occurred is life support being unfamiliar with the insert. For example, the size of the insert is critical to the seal and comfort experienced by the pilot. The bulk of the insert may also cause the size of the mask to feel smaller. Some pilots, therefore, may have needed a larger mask with the insert than they typically wore. This problem should be resolved with more training and familiarity with the mask insert.



Life support personnel pressure testing a pilot's mask with the new insert added using the manside pressure test

Four of 18 pilots **did not have their masks fit** by life support personnel. These pilots were included in the analysis. However, one of these pilots modified his mask insert after initial testing to improve comfort. This modification is discussed in Section 4.4.4.

Some volunteers stated that they **did not have seal or comfort problems with the current MBU-20/P oxygen mask**. The original plan was to remove these individuals from the evaluation, since the evaluators believed this would skew the results. However, these pilots also had thoughtful comments and suggestions concerning the insert and all pilots were included in the evaluation.

2.0 Methodology

2.1 Evaluation Methodology

The methodology developed for this evaluation is depicted in Figure 2-1. This methodology was documented in the Advance Aircrew Oxygen Mask Insert Evaluation Execution Plan, February 1997, developed by DESA, prior to transition to AFOTEC/TA.

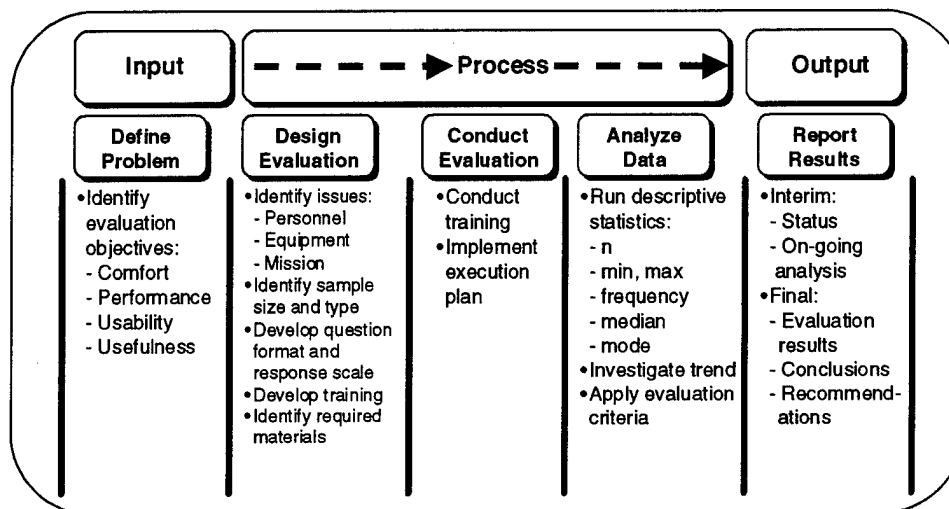


Figure 2-1. Evaluation methodology

2.2 Define Problem

The problem definition phase focused on interviews with two subject matter experts (SMEs), both retired fighter pilots, to determine the important objectives/issues associated with mask insert usage.

The interviews helped identify the major objectives of the evaluation: *determine mask seal and comfort with the mask insert*. The interviews also revealed some secondary objectives. These subobjectives included ease of use, compatibility with existing equipment, and performance of the insert material. Table 2-1 presents the objectives, subobjectives, and issues derived from the interview process.

2.2.1 Mask Seal

As seen in Table 2-1, the primary factors thought to directly affect mask seal were G-loading (positive and negative), altitude, and the ability to perform a valsalva maneuver. It is important to note these factors influence the seal provided by any mask, regardless of insert presence. Thus, while no insert-specific factors were identified, the focal point of the evaluation was the ability of the insert to alleviate the effect of these factors on mask seal.

Insert compatibility. As a subobjective, compatibility of the insert with existing equipment was thought to have a less direct impact on mask seal. Further, the issues associated with this subobjective

Table 2-1. Evaluation objectives and associated issues, derived through SME interviews.

Objectives		Issues to Be Assessed		
Subobjectives				
1.0 Does the insert improve mask seal?		G loading	Altitude	Valsalva
1.1 Is the insert compatible with existing equipment?		Microphone/speaking		Visor interference
		Mask release interference		Pressure breathing
		Vision interference		Regulator flow
		Helmet interference		
1.2 Is the insert material suitable for the mask environment?		Ambient conditions:		Contact/hygiene:
		–Heat		–Saliva/perspiration
		–Humidity		–Bacteria/fungus
		–Cold		–Growth
		–Vapor		–Deterioration
				–Cleaning/maintenance
2.0 Does the insert improve mask comfort?		Length of sortie		Irritation
		G-loading		Sagging
		Altitude		Changes over time
		Eyeglasses		
2.1 Is the insert easy to use?		Installation		Pre-fighting the mask
		Removal		Stability during
		Stay in/fall out		cockpit movement

were generally unique to the insert; that is, current masks were assumed not to interfere with the items or activities identified in Table 2-1 (microphone, visor, pressure breathing, etc.). However, because the insert has bulk, it may cause the mask to interfere with these items or activities.

Insert material. While this subobjective cannot be definitively addressed in a subjective evaluation, the intent of its inclusion was to capture any occurrences where ambient conditions or contact were thought to adversely affect the mask.

2.2.2 Mask Comfort

The second objective of the evaluation was to evaluate the extent to which mask comfort is improved by the insert. As with the first objective, most issues associated with comfort are not unique to the insert, but apply to any mask. Two issues emerged as generally unique to the insert—interference with eyeglasses and changes to the material over time. The former is a possible factor due to the bulk of the insert and the latter because material changes may impact comfort, as well as seal.

Insert Ease-of-Use. A subobjective of comfort is ease-of-use. While ease-of-use may not directly affect mask seal or comfort, it can affect whether the insert is used in the field.

2.3 Design of Evaluation

Design of the evaluation focused on questionnaire development and identification of sampling requirements. Additionally, test block locations and duration were specified.

2.3.1 Questionnaire Development

Two questionnaires were developed for this evaluation. A pre-evaluation questionnaire was designed to assess the seal and comfort of the current mask, without insert, and obtain mask size to provide the proper insert. The pre-evaluation questionnaire was administered in paper form, prior to the start of the assessment.

A post-evaluation questionnaire addressed the AAOM mask insert evaluation objectives. The questionnaire contained nine questions and was administered to pilots upon completion of their evaluation sorties. Response to the questions was done electronically on the AFOTEC/TA website using a laptop or desktop computer with internet access. The advantages of this data collection method were: 1) No travel required by the evaluators to collect data; 2) Accurate data entry; and 3) Uniform and non-biased presentation of the questionnaire to each pilot. For the few pilots who did not have internet access, personal or telephone interviews were conducted by the AFOTEC/TA evaluator. Both questionnaires can be found in Appendix A.

2.3.2 Question Format

Figure 2-2 illustrates the question format and response scale employed for the post-evaluation questions (pre-evaluation questions followed the same format, without the problem area section). This format reduced response burden, by simply checking problem areas. With the on-line data entry method, problem areas were only visible to the pilot if an "unacceptable" rating (4-6) was given. This was done to avoid biasing the pilot. A comment area was available for open-ended comments, regardless of the rating provided.

1. Rate the **SEAL** provided by your mask **WITH** the insert: _____

1 Completely Acceptable	2 Mostly Acceptable	3 Somewhat Acceptable	4 Somewhat Unacceptable	5 Mostly Unacceptable	6 Completely Unacceptable
-------------------------------	---------------------------	-----------------------------	-------------------------------	-----------------------------	---------------------------------

Problem Areas:

_____ Leaks at high Gs

_____ Leaks at negative Gs

_____ Leaks at high altitudes

_____ Leaks at low altitudes

_____ Leaks all the time

_____ Interferes with effective valsava maneuver

_____ Other (specify, in comment area)

*Visible only with
a 4, 5, or 6
rating*

Comment: _____

*Size of comment
area expandable
on website*

Figure 2-2. Question format

Response scale. The response scale illustrated in Figure 2-2 was a balanced, 6-point Likert scale using labels ranging from Completely Acceptable (1) to Completely Unacceptable (6). Figure 2-3 provides definitions for the scale labels.

Completely Acceptable - The insert is fine the way it is; no improvement required.
Mostly Acceptable - The insert meets its intended purpose; it could be improved to make it easier or more efficient.
Somewhat Acceptable - The insert meets its intended purpose with some reservations. Meets minimum requirements to accomplish mission/task.
Somewhat Unacceptable - Minor problems encountered with the insert. Task accomplished with some difficulty. Some degradation of mission/task accomplishment or accuracy.
Mostly Unacceptable - Major problems encountered with the insert. Task accomplished with great difficulty or accomplished poorly. Significant degradation of mission/task accomplishment or accuracy.
Completely Unacceptable - The insert is unusable or unsafe. Mission/task not accomplished due to equipment deficiencies or procedural limitations.

Figure 2-3. Response Scale Definitions

Table 2-2 provides the Traceability Matrix, linking objectives and subobjectives to evaluation questions (complete text of each question can be found in the post-evaluation questionnaire in Appendix A). The pre-evaluation questions relate to the seal and comfort of respondents' mask without the insert. As acceptance of the mask insert may be influenced by current mask performance, it was important to know if a need for improvement existed.

Table 2-2. Traceability Matrix: Evaluation Objectives to Questions

Objective 1.0 Does the insert improve mask seal?	1. Rate the SEAL provided by your mask WITH the insert.
Subobjective 1.1 Compatibility with existing equipment	3. Rate the COMPATIBILITY of the MASK INSERT with existing equipment.
Subobjective 1.2 Is the insert material suitable for the mask environment?	4. Rate the performance of the MASK INSERT MATERIAL .
Objective 2.0 Does the insert improve mask comfort?	2. Rate the COMFORT of your mask WITH the insert.
Subobjective 2.1 Is the insert easy to use?	5. Rate the overall USE of the MASK INSERT.

Finally, the questionnaire concluded with three "Yes/No" questions not included in the SME objectives. These questions were:

6. Did the insert **IMPROVE THE SEAL** of your mask?
7. Did the insert **IMPROVE THE COMFORT** of your mask?
8. Would you continue to **USE THE MASK INSERT**?

These questions were designed to test the hypothesis that the insert improves mask seal/comfort. The questions that form the body of the text (questions 1 through 5) were used to identify the underlying reasons for mask acceptance/rejection.

2.3.3 Sample Size Requirement

Development of the sampling matrix rested on several assumptions, identified by AFOTEC/TA and the insert developers:

- The F-16 pilot population is roughly 1,300.
- Forty percent of F-16 pilots have problems with their mask ($1300 \times 0.40 = 520$).
- The mask insert must improve performance and comfort for at least 75 percent of those with problems ($520 \times 0.75 = 390$).
- Therefore, the minimum *acceptance* rate is 30 percent ($390/1300$).
- A confidence level of 95 percent, with a 10 percent error rate is required.
- A one-tailed test of significance is appropriate.

Given these assumptions, a required sample size of 57 inserts was derived, using the formula for a binomial distribution described in Appendix B. However, it was recognized that after data had been collected, the actual acceptance rate could be used to determine if the confidence level and error rate requirements had been met. Thus, if 50 percent of 20 pilots (or more) reported the insert improved the seal/comfort of the mask, a statistical significance with a confidence level of 95 percent and an error rate of 10 percent would have been reached. Appendix B describes the computations supporting these sample size determinations.

Data Collection Schedule. The evaluation comprised a number of separate tests conducted at Kirtland AFB, New Mexico; Fort Smith, Arkansas; Buckley Field, Colorado; and Montgomery, Alabama. Coordination with life support personnel at each location was initiated by an Armstrong Laboratory representative. The AFOTEC/TA Project Leader followed up with data collection from each participating pilot and informal interviews with life support personnel. Data was collected piecemeal from April through November 1997. Delays were caused by pilot deployments, solicitation of willing guard units, and pilot schedules.



Female participant prepares to evaluate the mask insert.

3.0 Evaluation Execution

Execution of the evaluation included preparation of pilots and life support participants (see Figure 3-1), along with administering initial and final evaluation questionnaires. During the evaluation, the AFOTEC/TA Project Leader was available to respond to pilots' questions and concerns and collect inserts, should pilots voluntarily exit the evaluation. Each evaluation participant completed a pre-evaluation questionnaire prior to the start of the assessment. The post-evaluation questionnaire was administered to pilots upon completion of their evaluation sorties.

3.1 Mask Fitting Process

Life support personnel fitted a mask and insert for each pilot as part of the evaluation preparation. The fitting and testing procedure included performing a pressure test using the manside test set shown in Figure 3-2. This test allows the pilot to check the seal of the modified mask under different pressures. The pilot wears an upper pressure garment consisting of a pressurized vest. The vest pressure would be varied to simulate flight conditions while the pilot evaluated the mask insert seal. The tester can simulate pressures up to 9 to 10 G forces². Figure 3-3 shows a pilot testing the seal of his mask with the insert added.



Figure 3-1. An Armstrong Laboratory representative demonstrates to life support personnel at Buckley ANG how to use the mask insert.

3.2 Pilot Testing

It was planned that each pilot would fly with the insert for at least two sorties, unless they chose to quit the evaluation, and each sortie would be a minimum of 1 hour. Each pilot had their original mask and an unmodified mask with insert in order to swap masks between sorties to evaluate the seal and comfort of the altered mask. Pilots answered questionnaires as soon as possible after the test flights. All responses were confidential. Quotes from participants are used in this report by pilot permission.

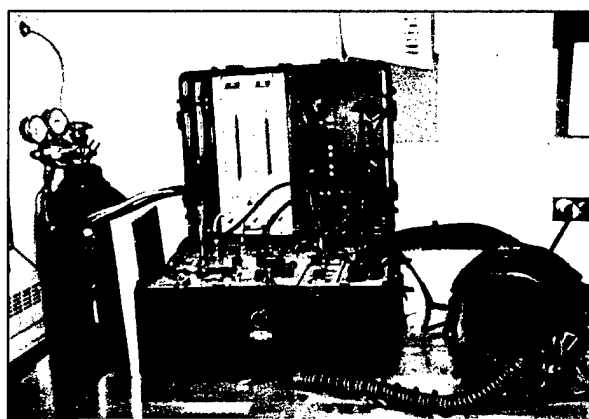


Figure 3-2. The manside pressure tester with pilot helmet used to test the seal/fit of the pilot's mask.

²G Forces Definition

G = Gravity; 1G = Normal weight at sea level; 2Gs = Twice the normal weight at sea level; 10Gs = Ten times the normal weight at sea level



Figure 3-3. Pilots were fitted with a mask and insert as part of the evaluation preparation at Buckley ANG.

3.3 Data Collection

Data collection involved administering the pre-evaluation questionnaire addressing *current* mask seal and comfort, and a post-evaluation questionnaire addressing mask seal and comfort with the *mask insert*. The pre-evaluation questionnaire was administered via hard copy in a group setting by either life support or by the AFOTEC/TA Project Leader. All pilot demographic information was collected at this time. These questionnaires were entered into the database by AFOTEC/TA.

Pilots responses were stored in the database, identified by social security number (SSN). Some pilots chose to exit the evaluation (by informing life support and returning the insert) before the evaluation was completed.

Demographic data were collected to assist analysis during the evaluation. Table 3-1 shows the demographic data fields and their purpose.

Table 3-1. Demographic Data

Data Field	Purpose
SSN (4)	Track pilot status & responses
Last Name	Track pilot status & responses
Gender	Classify sample/responses
Rank	Classify sample/responses
Time in Rank	Classify sample/responses
Total Flying Hours	Classify sample/responses
Hours Flying F-16	Classify sample/responses
Number of sorties flown with mask insert	Classify sample/responses
Insert ID	Track inserts

4.0 Results

4.1 Number of Participants

There was a general reluctance on the part of the pilot population to state that they were having a problem with the MBU-20/P oxygen mask and request alterations of their current mask. One possible reason for this reluctance was the requirement to fit the mask with an insert and perform a pressure test. Another reason for poor pilot participation was the lack of support from the command structure of the participating units. As a result, only 18 pilots participated in the evaluation. Although the number of participants is low, the data gathered is still useful to the AAOM program.

4.2 Population Demographics

Demographic information from the pre-evaluation questionnaire was analyzed to determine if the sample population was representative of F-16 pilots as a whole.

There were 18 pilots participating in this evaluation. They ranged from O2 to O6 in rank, with one non-American and one female pilot. They had F-16 flight experience ranging from a minimum of 410 hours to 1,200 hours. Table 4-1 shows the rank of the participants, and Figure 4-1 shows their average flight experience. The participants used all mask insert sizes [small/narrow (S/N), medium/narrow (M/N), medium/wide (M/W), and large/wide (L/W)] during the evaluation as shown in Figure 4-2.

Table 4-1. Rank of evaluation participants

Rank	O2	O3	O4	O5	O6
Number of Participants	1	7	4	3	2

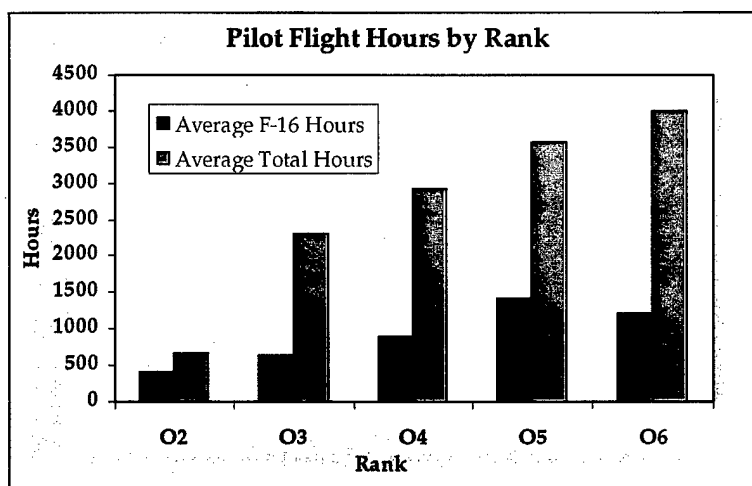


Figure 4-1. Average flight experience of evaluation participants.

4.3 Mask Without Insert

Pilots were asked in the pre-evaluation to rate their current mask, without insert, in terms of seal and comfort, and provide comments as necessary to explain their ratings. The first question addressed the seal of the mask without the insert. The responses ranged from "Completely Acceptable" to "Somewhat Acceptable," as shown in the graph of Figure 4-3. Positive comments from the participants included "Good fit, no leaks or problems."

Despite the acceptable ratings, there were complaints, including the following:

- *Does the job - Just not comfortable. Also, does not allow valsalva.*
- *Mask has to be almost uncomfortably tight to maintain a good seal during peak combat edge operations.*
- *Leaks under G when pressure breathing begins.*
- *It leaks around the nose.*
- *Mask seals fine, sometimes leaks under high G - leaks while moving head.*
- *It has never sealed really right. I have to tighten it extremely tight to where it hurts.*

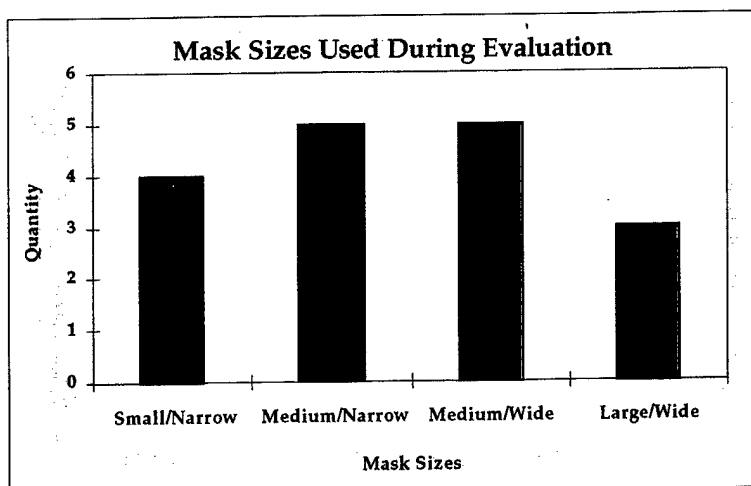


Figure 4-2. Mask sizes used during evaluation. (One pilot did not provide mask size.)

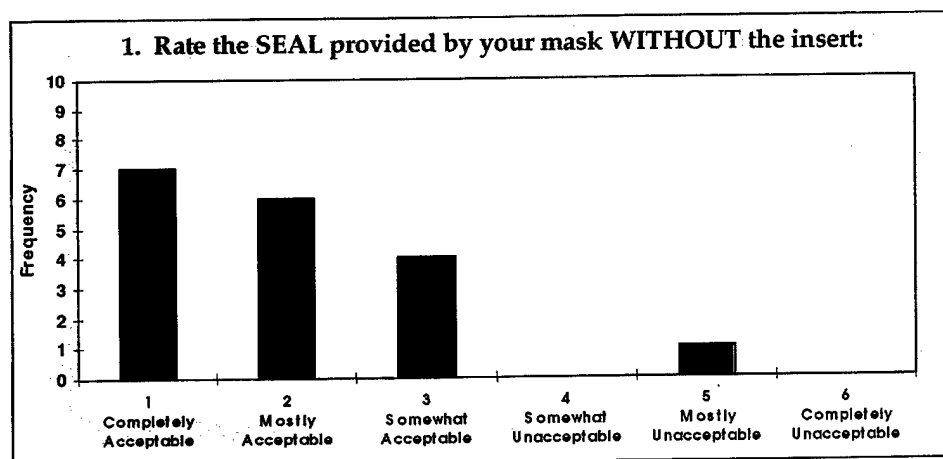


Figure 4-3. Only one pilot stated an unacceptable rating for his mask seal, however, there is a general reluctance of pilots to admit problems.

All five pilots rating the seal as "Somewhat Acceptable" or below, indicated they had leak problems in their comments.

Pilots were also asked to rate the **comfort** of the current mask. The responses ranged from "Completely Acceptable" to "Completely Unacceptable" as shown in Figure 4-4. Positive comments concerning the comfort of the present mask included "**Completely Comfortable**" and "**Not as good as a 12/P, but acceptable.**" Complaints concerning the comfort of the current mask included:

- *Not very!*
- *Tightness in nasal area is better than the old style non combat-edge but still present*

- *There's not enough room for my nose - it hits the microphone. The old mask (I2/P) (Prior to the combat edge) fit like a glove.*

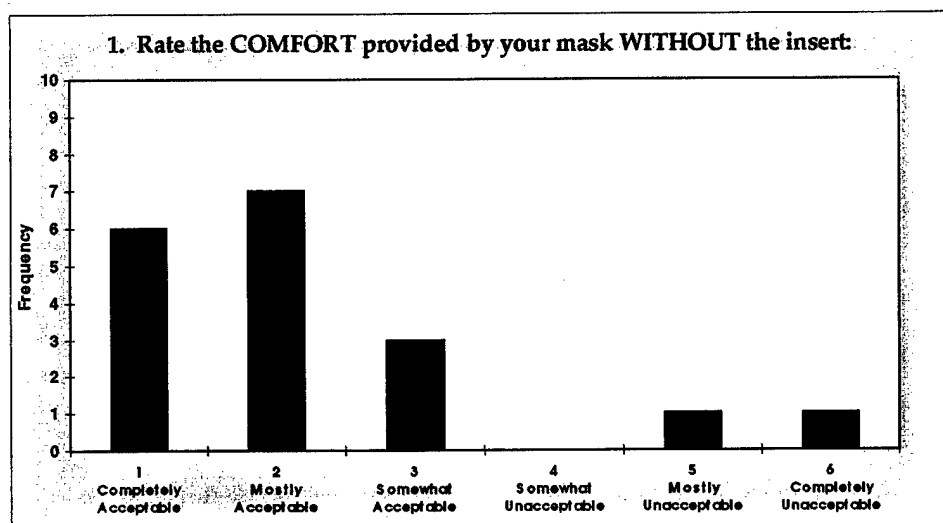


Figure 4-4. There were more comfort problems than seal problems.

4.4 Insert Evaluation

During the course of the evaluation, 18 pilots used the insert on 53 sorties and completed evaluation questionnaires. Two pilots completed a total of 10 sorties each with the mask insert, while six pilots completed only one sortie with the insert. The maximum number of hours using the insert on any given sortie was 2.7, and the minimum was 0.5. Figure 4-5 shows the maximum time and number of sorties flown by pilot with the insert.

4.4.1 Objective 1.0: Insert Seal Evaluation

Pilots rated the seal provided by the mask with the insert as shown in Figure 4-6. This chart categorizes pilot responses according to whether they indicated seal problems with the original mask. Five of the 18 pilots had been identified as having seal problems from the pre-evaluation questionnaire. Note that 83.3 percent of all pilots rated the seal of the mask with insert in the "Acceptable" range (Completely, Mostly, or Somewhat Acceptable), and 16.7 percent rated the seal in the "Unacceptable" range (Completely, Mostly, or Somewhat Unacceptable). Also note that the ratings improved for all pilots with previous seal problems. **This implies the insert does improve the seal for pilots who need a better seal.**

The pilots who responded in the unacceptable range were also asked to describe any leakage problems by using a check list of possible problem descriptions and entering comments. The responses are shown in Table 4-2.

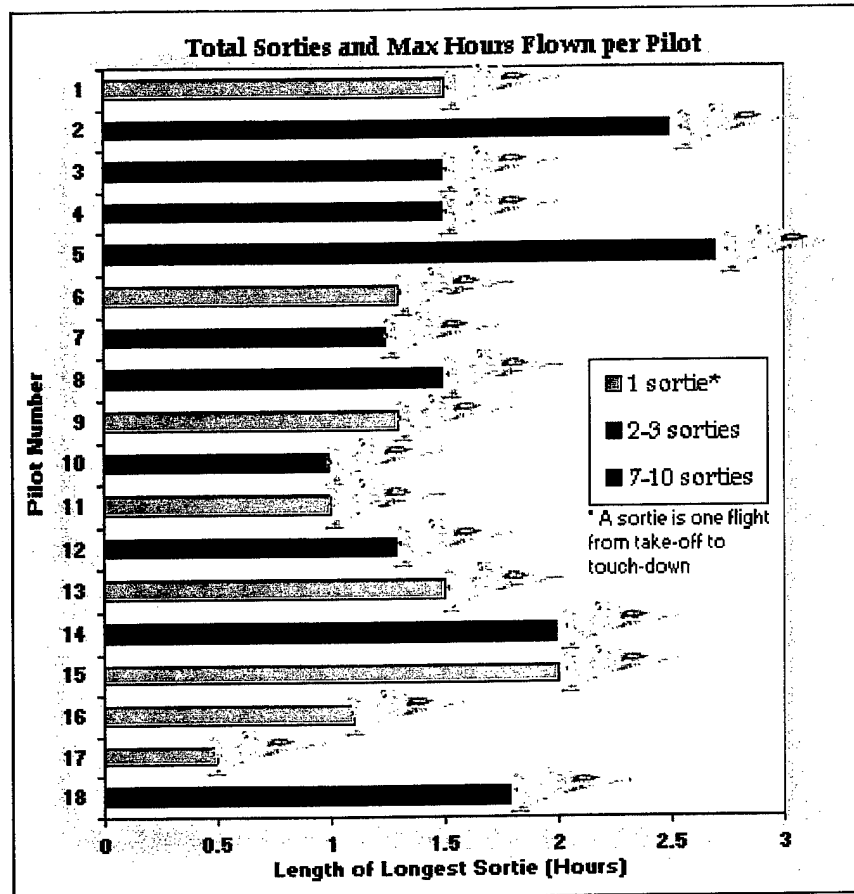


Figure 4-5. Two pilots flew at least 2.5 hours in one sortie and at least seven sorties total.

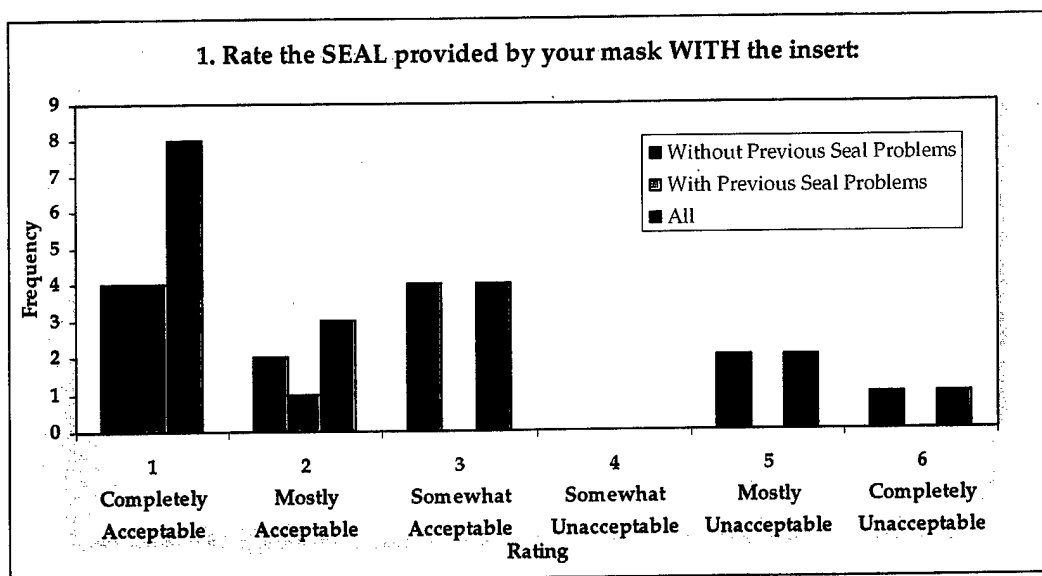


Figure 4-6. Most pilots rated the seal provided by the mask with the insert in the "Acceptable" range. Only five pilots had previous seal problems; four of them rated the new seal as "Completely Acceptable" and one rated it as "Mostly Acceptable."

Comments concerning the seal of the mask with the insert included:

- *The seal far exceeded my expectations and it's much more comfortable.*
- *The seal was great.*
- *Would work fine if someone had a leak problem.*
- *The mask slipped off and air came over the top of it into my eyes. This mask was not refitted for the insert.*
- *It didn't seal as well with the insert as without the insert. The insert made the seal more rigid.*

Table 4-2. Responses to potential mask insert problem areas.

Problem Areas:	Responses
Leaks at high Gs	2
Leaks at negative Gs	0
Leaks at high altitudes	1
Leaks at low altitudes	1
Leaks all the time	1
Interferes with effective valsalva maneuver	1

Each pilot's rating of the mask seal *without* the insert was compared to the rating of the mask seal *with* the insert. Figure 4-7 shows that information summarized in three categories "Better," "Same," and "Worse," and categorized by previous seal problems.

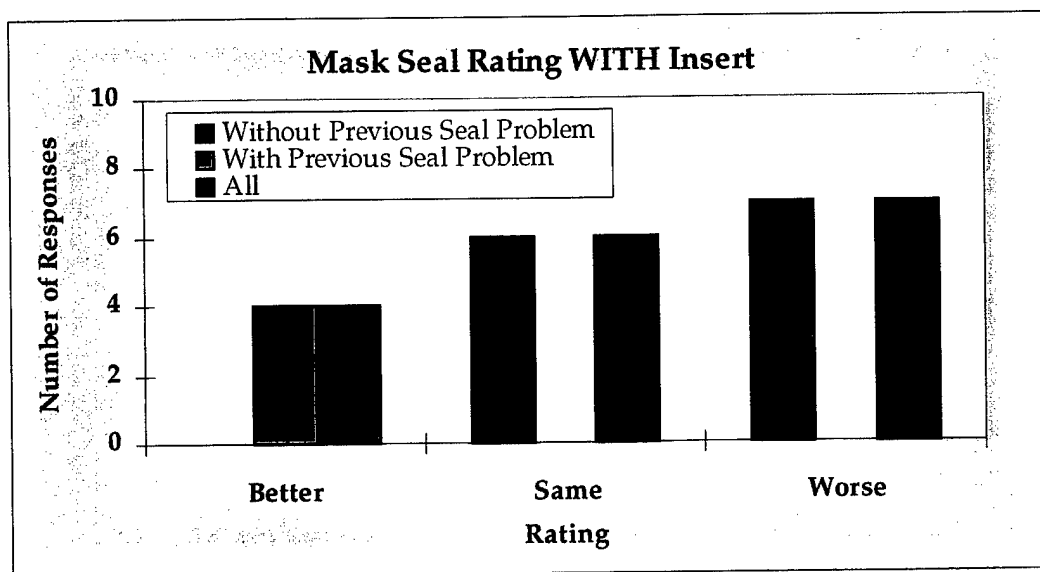


Figure 4-7. All pilots who had some previous seal problems rated their new seal as better than before.

Seal Evaluation Summary. Most pilots rated the seal with the insert in the acceptable range: 83.3 percent acceptable and 16.7 percent unacceptable. Additionally, all pilots reporting previous seal problems rated the seal of the mask with the insert as better than the seal of the mask without the insert. Problems were identified due to the insert slipping and the rigid nature of the insert.

4.4.2 Subobjective 1.1: Compatibility with Existing Equipment

Compatibility of the insert with existing equipment was addressed as a subobjective of the mask seal because the insert has bulk and therefore may cause interference with microphone, visor, etc. The

responses, shown in Figure 4-8 indicate that 72.2 percent of the pilots rated the mask insert as acceptable in terms of compatibility with existing equipment.

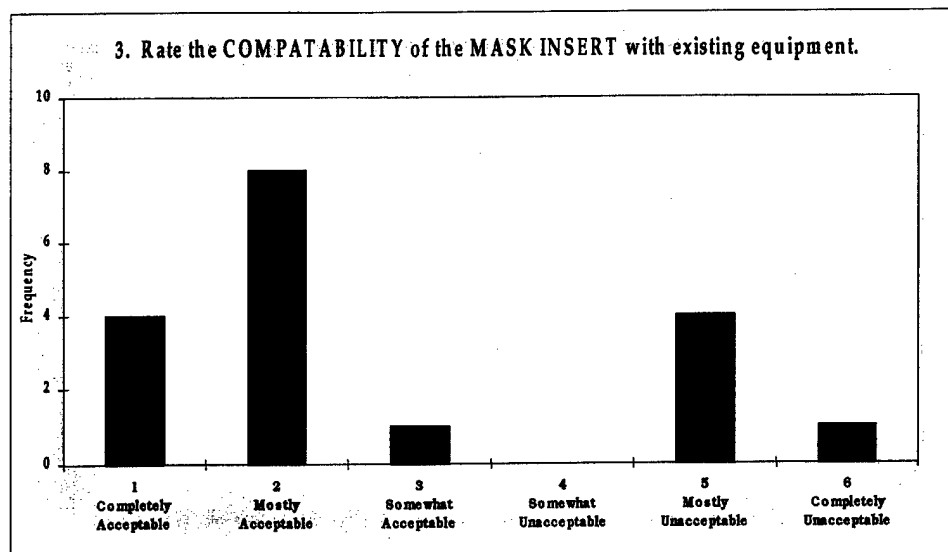


Figure 4-8. Compatibility of the mask insert with existing equipment.

Pilots who responded in the unacceptable range were also given the opportunity to respond using a check list of potential problem areas and using comments. The check list responses are shown in Table 4-3.

The comments provided included the following:

- *Did not notice very much except that it was a little harder to valsalva with the mask on.*
- *Not completely compatible as my mask STILL does not completely allow for a valsalva.*
- *Interferes with my ability to talk.*

Table 4-3. Problem areas for mask insert compatibility question.

Problem Area	Responses
Interferes with vision	0
Interferes with microphone use	0
Interferes with mask release	1
Interferes with visor	1
Adversely affects pressure breathing	2
Adversely affects regulator flow	0

Compatibility Summary. Seventy-two percent of the pilots rated the insert in the acceptable category, however there were compatibility problems reported such as mask release, visor interference, adverse affects during pressure breathing, problems performing the valsalva maneuver, and problems talking.

4.4.3 Subobjective 1.2: Insert Material Suitability

The intent of this subobjective was to capture any occurrences where ambient conditions or contact were thought to adversely affect the mask. This would include the operating environment such as heat, cold, and humidity as well as the human operating environment resulting from skin contact, saliva, perspiration, etc. The question and responses are graphically shown in Figure 4-9.

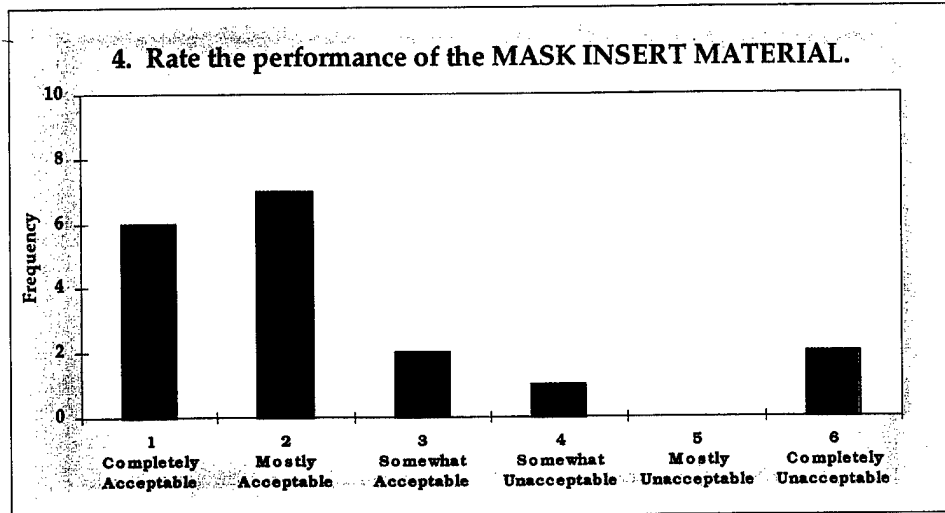


Figure 4-9. Although two pilots stated the mask insert material was affected by skin contact, the issue was actually a discomfort problem of the mask material on the skin.

Pilots who responded in the unacceptable range were also given the opportunity to respond using a check list of potential problem areas and using comments. The check list responses are shown in Table 4-4.

The comments provided included the following:

- *Did not notice any material wear.*
- *Might not last that long, but I had no problems with it.*
- *The only problem was that it's porous and absorbs sweat and moisture.*

Insert Material Suitability Summary. Most pilots rated the performance of the insert material as acceptable (83.3 percent), and few problems were reported. However, concern was raised about the long-term durability and hygiene issues relating to the porous insert material absorbing sweat and moisture.

Table 4-4. Problem areas for mask insert material question.

Problem Area	Responses
Affected by heat	0
Affected by cold	0
Affected by humidity	0
Affected by oxygen	0
Affected by skin contact	2
Deteriorated over time	0

4.4.4 Objective 2.0: Does the insert improve mask comfort?

The second objective of the evaluation was to determine the extent to which mask comfort is improved by the insert. Pilots were asked to rate the **comfort** of the mask *with* the insert. The responses, graphed in Figure 4-10, show that only 33.3 percent of all pilots rated the mask comfort in the "Acceptable" range, while 66.7 percent rated the mask comfort in the "Unacceptable" range. **This is a reversal of the comfort ratings for the mask without the insert.** Once again, the ratings shown in the figure are categorized according to presence or absence of a prior comfort problem.

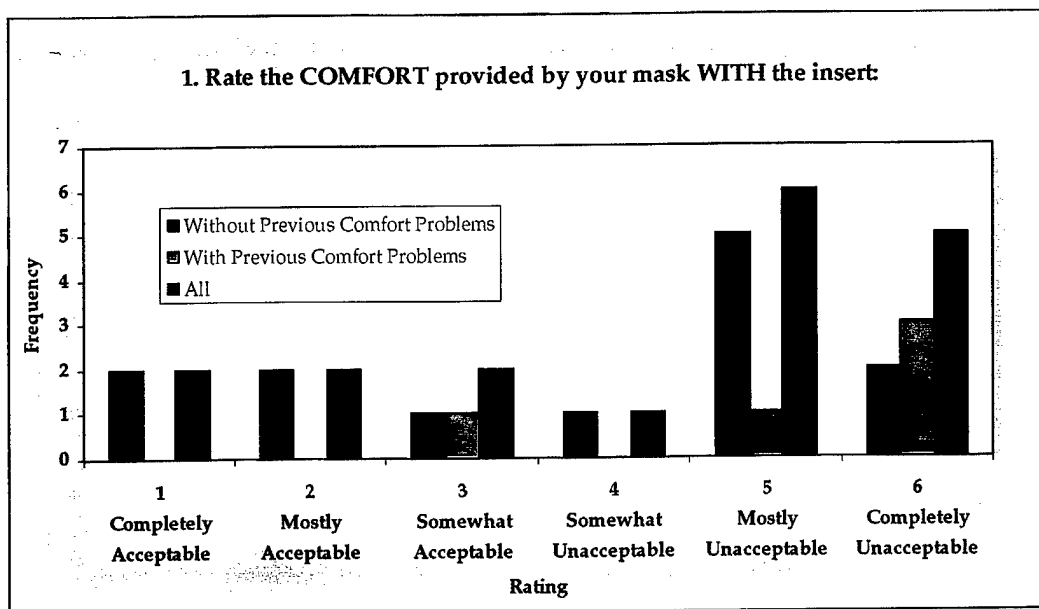


Figure 4-10. There were more unacceptable comfort ratings than expected. Out of the five pilots who had previous comfort problems, only one rated the comfort of the insert as improved.

The 12 pilots responding in the unacceptable range were asked to check a list of potential problem areas and provide comments. They checked 31 problem areas as shown in Table 4-5. **Seven of the 12 pilots indicated the insert caused irritation. Four of the 12 pilots indicated the insert was uncomfortable for lengthy use, and eight indicated the mask was uncomfortable at all times.**

The comments provided included the following:

- *Very comfortable to wear.*
- *Comfortable, the reason is the increased surface area of the seal.*
- *A little confining but opened nasal area (improvement) and still kept the seal.*
- *Mask was very comfortable, no adverse comfort was noticed.*
- *It's too rough.*
- *Too hard.*
- *The mask was too hard and became very uncomfortable after 10 minutes.*
- *The foam may LOOK smooth, but it is exceptionally rough on your face and is EXTREMELY irritating. The rubber seal of the mask did not cover the foam of the insert. It was like cutting the top off a tin can and pressing it against your face. It felt like sandpaper.*
- *This caused irritation on the bridge of my nose.*

Table 4-5. Problem areas for mask insert comfort question.

Problem Area	Responses
Has to be tightened to a point that it is uncomfortable	3
Interferes with eyeglasses	1
Causes irritation	7
Causes the mask to sag	2
Uncomfortable at higher altitudes	0
Uncomfortable at high Gs	3
Uncomfortable at negative Gs	0
Uncomfortable during combat maneuvers	3
Uncomfortable for lengthy use	4
Uncomfortable at all times	8

- *It felt too small between the top of my nose to the bottom of my mouth the inner part of mask.*
- *The bottom part, under the lip, across the chin part of the insert stuck up past the mask and it rubbed the skin making it raw. I trimmed off part of the insert material to make it more comfortable. I flew three sorties with the modified insert and it was great. (Figure 4-11 shows the mask insert modified by this pilot.)*

Comparison of comfort evaluations with and without the mask insert is shown in Figure 4-12.

Most pilots also indicated the mask insert was both restrictive and an irritant. This was especially true around the nose and chin, where the rigidity of the mask caused it to rub. The foam insert material, while appearing soft, feels rough to the user when inserted in the mask. The roughness is more apparent when the mask is under pressure because the expansion of the mask exposes the insert material. The "roughness" may be due to the edge of the face piece being pressed against the face by the insert. This would create a sharp edge of silicone rubber pressing against the skin. Apparently, from laboratory testing, the insert designers/manufacturers knew there might be a problem with bottom lip area.

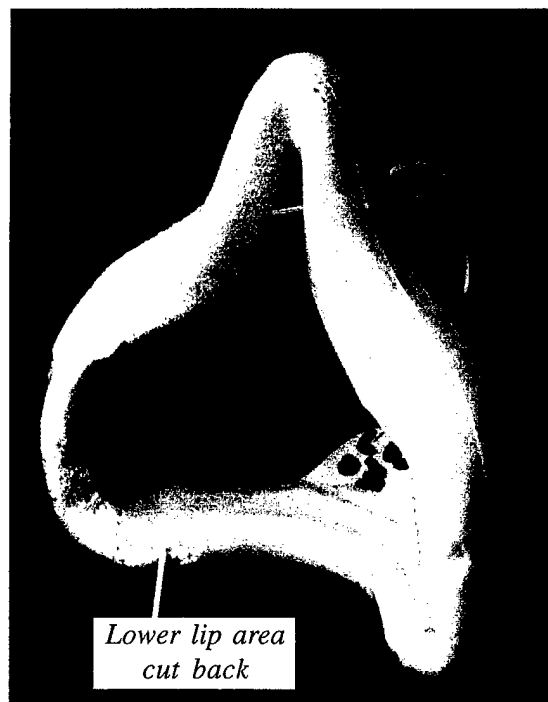


Figure 4-11. One pilot at Kirtland AFB modified his mask to increase comfort. (The inside lower edge was cut back with a razor.)

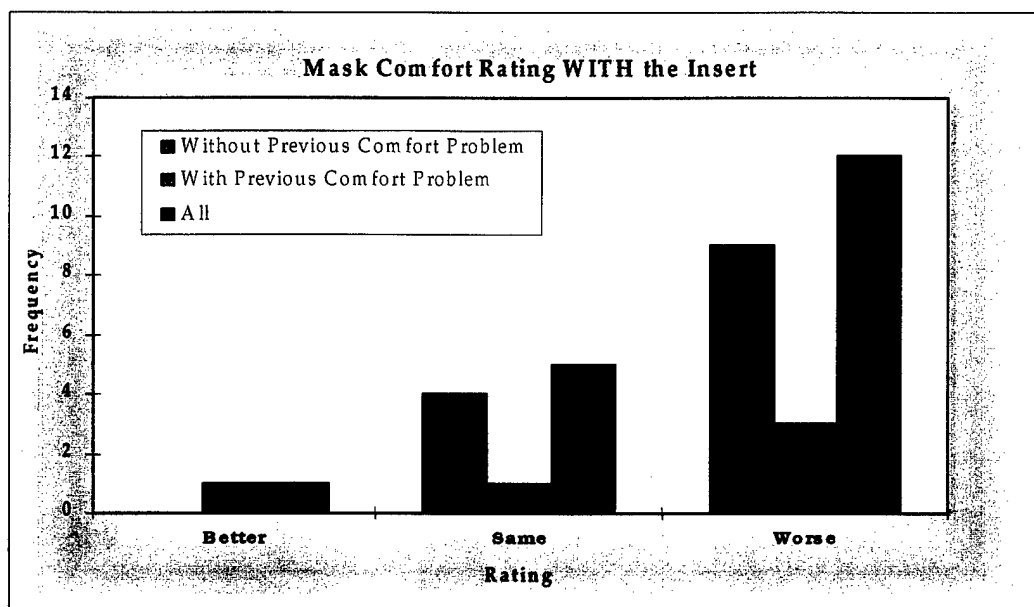


Figure 4-12. Comparison of comfort rating with and without the mask insert.

Comfort Summary. Only 33.3 percent of the pilots rated the mask comfort in the "Acceptable" range, while 66.7 percent rated the mask comfort in the "Unacceptable" range. Although the insert apparently did not improve the comfort of the mask, as one pilot put it, *"Flying a high performance jet is not a comfortable thing to do."*

4.4.5 Subobjective 2.1: Insert Ease-of-Use

A subobjective of comfort is ease-of-use. While ease-of-use may not directly affect mask seal or comfort, it can affect whether the insert will be used in the field. The responses are shown in Figure 4-13 in which 83.3 percent of the pilots rated the overall use of the mask insert in the "Acceptable" range.

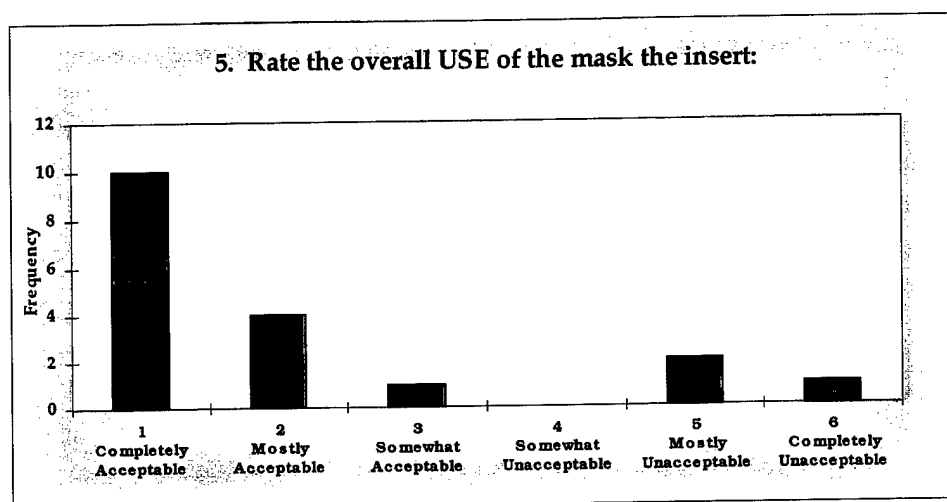


Figure 4-13. The overall USE of the insert referred to its "ease-of-use." The actual installation of the inserts was done by life support personnel.

Pilots who responded in the unacceptable range were also given the opportunity to respond using a check list of potential problem areas and using comments. The check list responses are shown in Table 4-6.

The comments provided included the following:

- *N/A done by life support.*
- *Did not remove the insert at any time, left that up to life support.*
- *Ripped face form during flight.*

Insert Ease-of-Use Summary. Most pilots reported the insert ease-of-use to be in the "Acceptable" range (83.3 percent). This did not seem to be a large issue and resulted in few problems reported or comments noted. However, it should be noted that the pilots did not have to install or remove the inserts (unless they removed it by choice in-flight). Interviews with life support personnel revealed they had no difficulties with the use of the insert.

Table 4-6. Problem areas for mask insert use question.

Problem Area	Responses
Installation is difficult	0
Removal is difficult	0
Impacts pre-flighting of mask	1
Does not stay secure while mask is hanging	0

4.4.6 Additional Questions

Three questions were included by the evaluator for hypotheses testing. The questions, numbered 6, 7, and 8 on the questionnaire, were:

6. Did the insert **IMPROVE THE SEAL** of your mask (Y/N)?
7. Did the insert **IMPROVE THE COMFORT** of your mask (Y/N)?
8. Would you continue to **USE THE MASK INSERT** (Y/N)?

Responses to question 6, seal improvement, were evenly divided (50 percent “Yes” and 50 percent “No”) as shown in Figure 4-14. Responses to question 7, improved comfort, were overwhelmingly negative (15.7 percent “Yes” and 84.2 percent “No”), as shown in Figure 4-15. The final question addressed pilot willingness to continue using the mask insert. The responses are shown in Figure 4-16. In the figure, note that all five pilots reporting seal problems with the original mask responded that they would continue to use the mask insert.

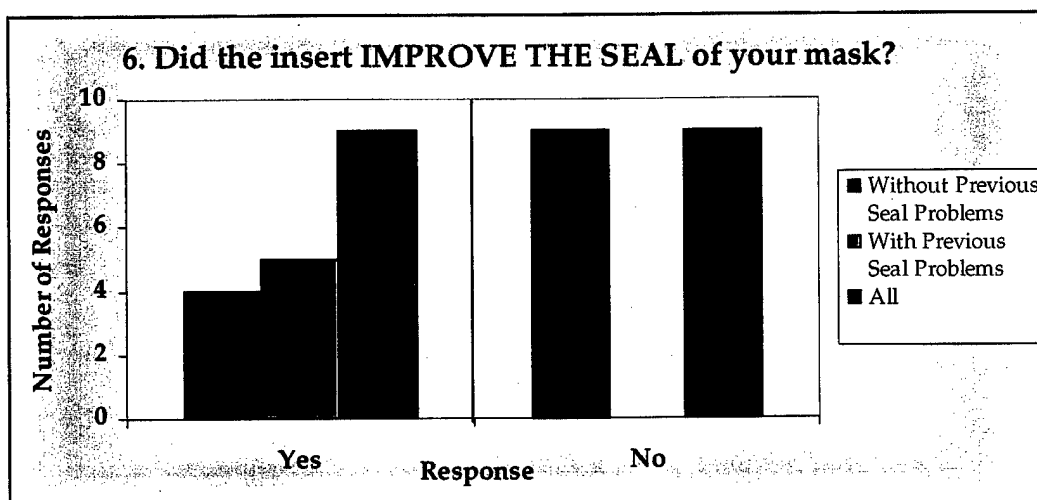


Figure 4-14. Pilots were evenly divided on the question of improved seal with the mask insert. The insert improved the seal for all pilots who had a seal problem. Four pilots without a previous seal problem responded that the insert improved the seal of their mask.

A minimum sample size of 20 was required for hypothesis testing. Although that minimum size was not achieved, additional information can be gleaned from the responses. For example, Figure 4-17 shows pilot responses to question 6, seal improvement, and question 8, continued use. In the figure, note that all pilots indicating that the mask did not improve the seal also indicated they were not willing to wear the mask with the insert again. A similar comparison of comfort improvement and continued use is shown in Figure 4-18. It is interesting to note that four of the seven pilots willing to use the mask again also found the mask with insert did not improve the comfort.

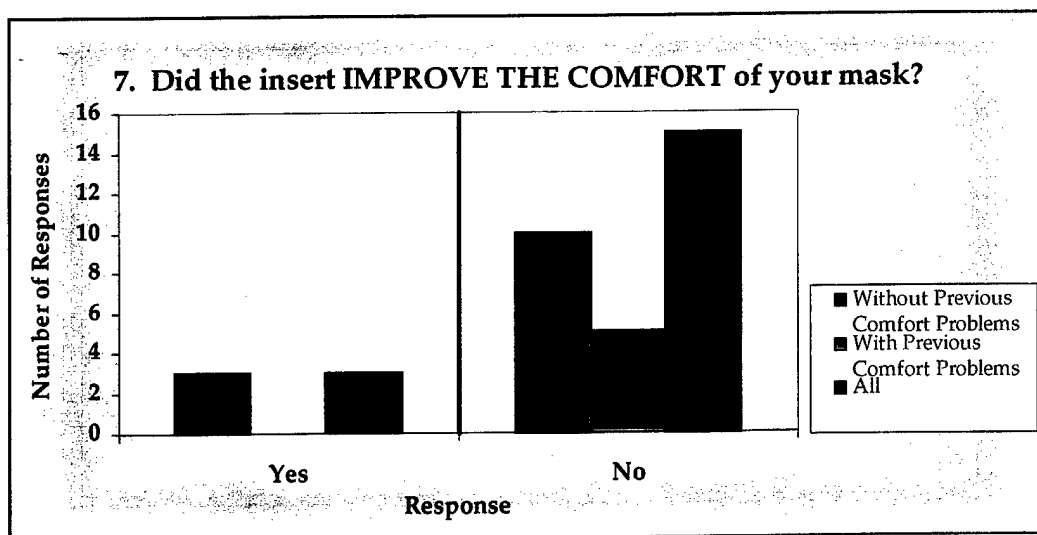


Figure 4-15. None of the pilots who reported comfort problems with the original mask got improvement with the insert. However, three pilots who were not known to have comfort problems reported an improvement in comfort with the insert.

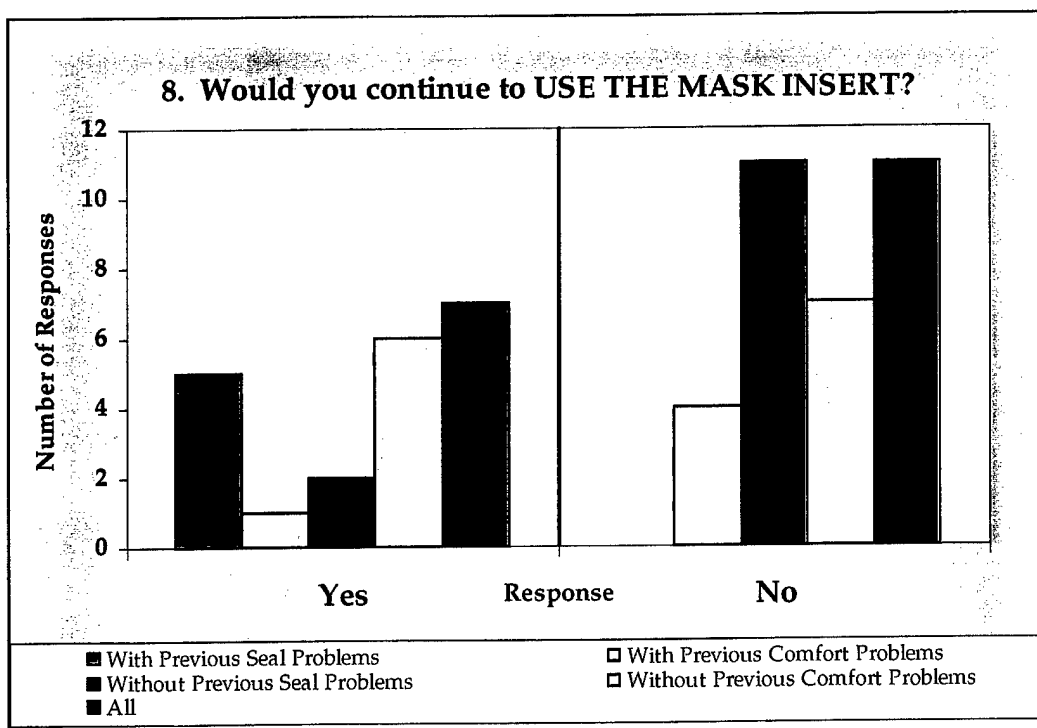


Figure 4-16. Most pilots would not choose to continue to use the mask insert. Of those with previous seal problems, all five would continue to use the insert. Only one pilot with previous comfort problems would continue to use the insert.

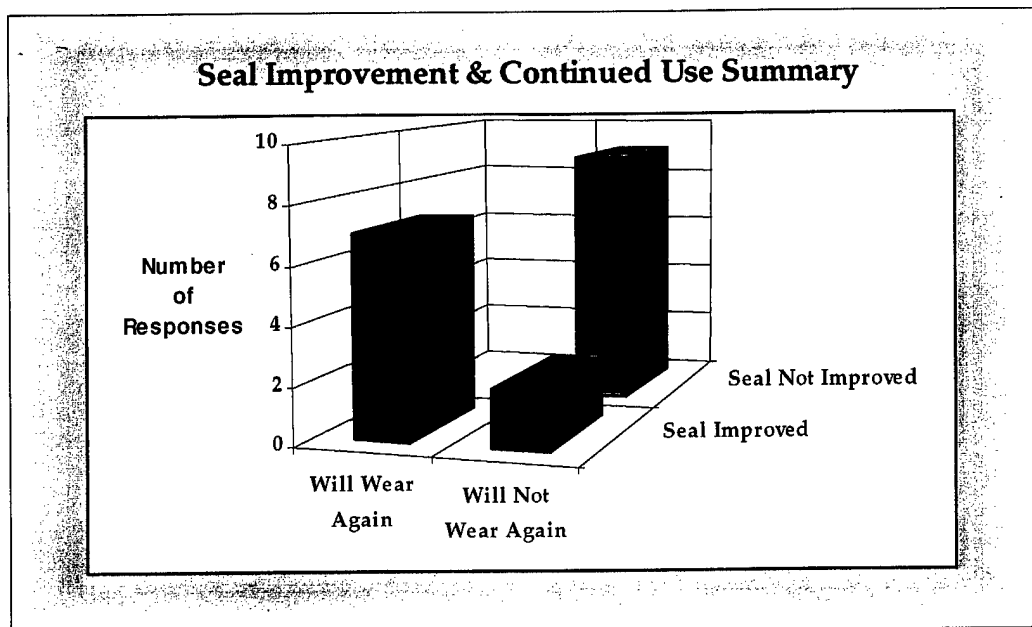


Figure 4-17. Comparison of seal improvement and continued use responses.

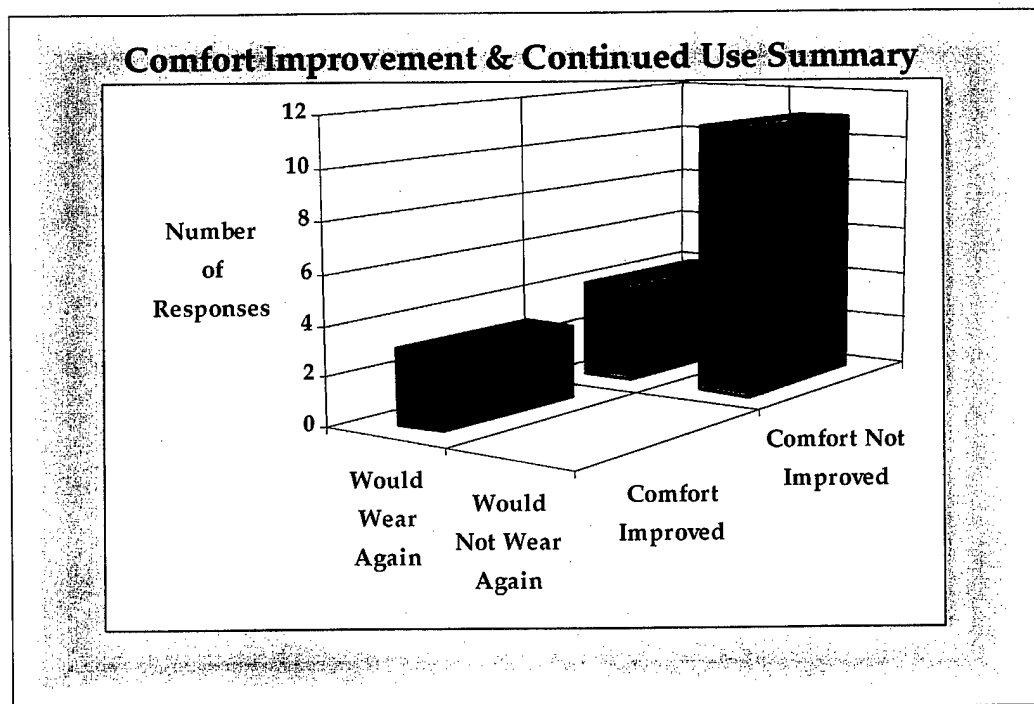


Figure 4-18. Comparison of comfort improvement and continued use responses.

5.0 Discussion

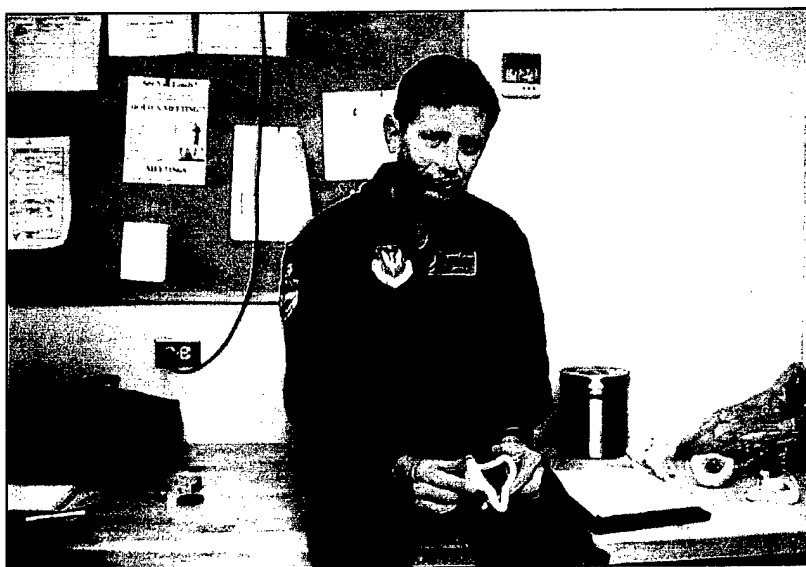
A FOTEC/TA was asked by ALCFT to plan and conduct an evaluation of a prototype mask insert designed to enhance the comfort and seal performance of the MBU-20/P silicone rubber face piece for the oxygen mask. The field evaluation was conducted using ANG pilots assigned to the following Fighter Wings:

- Kirtland AFB, New Mexico ANG, 150th Fighter Wing
- Fort Smith, Arkansas, Arkansas ANG, 188th Fighter Wing
- Buckley Field, Colorado, 140th Fighter Wing
- Montgomery, Alabama ANG, 187th Fighter Wing
- United Kingdom Air National Guard.

This evaluation addressed the *operational use* of an aircrew oxygen mask insert in which the seal and comfort of the mask with the insert were evaluated. The primary issues/factors thought to directly affect mask seal were G-loading (positive and negative), altitude, and the ability to perform a valsalva maneuver.

The original sampling goal was to have 57 pilots *that have problems* with the MBU-20/P oxygen mask participate in the evaluation. A minimum acceptance rate of 30 percent with a confidence level of 95 percent, and 10 percent error rate would have required 23 of the 57 participants rate the mask insert as improving performance and comfort.

There was a general reluctance on the part of the pilot population to state they were having a problem with the MBU-20/P oxygen mask and alter their current mask. One of the reasons for this reluctance was the requirement to fit the mask with an insert and perform a pressure test. Another reason for the poor participation was the lack of support from the command structure of the participating units. As a result, only 18 pilots participated in the evaluation. While the number of participants was low, the data gathered is still useful to the AAOM program.



Buckley ANG pilot volunteer preparing to evaluate insert.

Most of the pilots indicated that the **seal of the mask with the insert was improved at the cost of comfort**. However, as one pilot stated, "Flying a high performance jet is not a comfortable thing to do."

Most pilots also indicated that the mask insert was both restrictive and an irritant. This was especially true around the nose and chin, where the rigidity of the mask caused it to rub. The foam insert material, while appearing soft, feels rough to the user when inserted in the mask. The roughness is more apparent when the mask is under pressure, because the expansion of the mask exposes the insert material. The "roughness" may be due to the edge of the face piece seal being pressed against the face by the insert. This would create a sharp edge of silicone rubber pressing against the skin.

Pilots also indicated reservations concerning the long-term durability of the insert material and hygiene issues relating to the porous insert material absorbing sweat and moisture.

There were five pilots *that indicated they have problems* with the MBU-20/P oxygen mask. All five pilots indicated the insert improved the seal and they would chose to wear the mask in the future. However, even these were split on the issue of improved comfort.

It should be noted, many of the pilots thought the present MBU-20/P oxygen mask was not comfortable *with or without the insert*. As one pilot stated, "For a solution to the comfort of the mask, the mask itself needs to be redesigned."

While there was not sufficient pilot participation to generate statistically significant conclusions, the following observations are offered:

- The insert appears to improve the seal of the MBU-20/P oxygen mask.
- The MBU-20/P oxygen mask is uncomfortable and for many pilots, the insert makes the mask more uncomfortable.
- Under pressure, the insert material is exposed to the pilot's face and:
 - Feels rough
 - Rubs against the bridge of the nose
 - Rubs against the bottom lip area
 - Creates a sharp edge of silicon rubber pressing against the skin
- Units were solicited on a voluntary basis, and some were not willing to participate.
 - Participation needs to be obtained from a level above the life support (in the command structure) to ensure having adequate numbers of participants.
- Two pilots were grateful for the insert as it improved the seal so much they wanted to keep and continue to use the prototype insert used for the evaluation.
- More testing is needed to make a statistical determination regarding the benefits of the mask insert.

APPENDIX A
Human Factors Questionnaire
Instructions

Your responses to this questionnaire are very important in helping to evaluate the performance and comfort of the mask. These questions will help the evaluation team understand the problems you may be experiencing with your mask and to analyze evaluation results appropriately. Your name and individual answers will be kept strictly confidential.

For each question:

1. Circle or check the appropriate rating
2. Use the comment area to explain UNACCEPTABLE ratings (1, 2, 3) and/or provide additional comments.

Rating Scale and Definitions

1	2	3	4	5	6
Completely Acceptable	Mostly Acceptable	Somewhat Acceptable	Somewhat Unacceptable	Mostly Unacceptable	Completely Unacceptable

Completely Acceptable - The insert is fine the way it is; no improvement required.

Mostly Acceptable - The insert meets its intended purpose; it could be improved to make it easier or more efficient.

Somewhat Acceptable - The insert meets its intended purpose with some reservations. Meets minimum requirements to accomplish mission/task.

Somewhat Unacceptable - Minor problems encountered with the insert. Task accomplished with some difficulty. Some degradation of mission/task accomplishment or accuracy.

Mostly Unacceptable - Major problems encountered with the insert. Task accomplished with great difficulty or accomplished poorly. Significant degradation of mission/task accomplishment or accuracy.

Completely Unacceptable - The insert is unusable or unsafe. Mission/task not accomplished due to equipment deficiencies or procedural limitations.

Mask Size: _____	Insert ID: _____
Last Name: _____	Last four digits of SSN: _____
Gender: _____	Location (Circle one): KAFB HAFB
Rank: _____	Time in Rank: _____
Total Flying hours: _____	Hours Flying F-16: _____

1. Rate the **SEAL** provided by your mask **WITHOUT** the insert:

1	2	3	4	5	6
Completely Acceptable	Mostly Acceptable	Somewhat Acceptable	Somewhat Unacceptable	Mostly Unacceptable	Completely Unacceptable

Comment:

2. Rate the **COMFORT** of your mask **WITHOUT** the insert:

1	2	3	4	5	6
Completely Acceptable	Mostly Acceptable	Somewhat Acceptable	Somewhat Unacceptable	Mostly Unacceptable	Completely Unacceptable

Comment:

POST-EVALUATION QUESTIONNAIRE

Human Factors Questionnaire Instructions

Your responses to this questionnaire are very important in helping to evaluate the performance and comfort of the mask insert. Your answers will help identify improvements and your name and individual answers will be kept strictly confidential.

For each question:

1. Select the appropriate rating
2. If you experience a problem, select *all* problem areas that apply
3. Any time you select a ***Completely Unacceptable, Mostly Unacceptable, or Somewhat Unacceptable***, you **MUST** select at least one problem area. You may select as many as you like.
4. Use the comment area to explain problem areas, add other problem areas and/or provide additional comments.

Rating Scale and Definitions

1	2	3	4	5	6
Completely Acceptable	Mostly Acceptable	Somewhat Acceptable	Somewhat Unacceptable	Mostly Unacceptable	Completely Unacceptable

Completely Acceptable - The insert is fine the way it is; no improvement required.

Mostly Acceptable - The insert meets its intended purpose; it could be improved to make it easier or more efficient.

Somewhat Acceptable - The insert meets its intended purpose with some reservations. Meets minimum requirements to accomplish mission/task.

Somewhat Unacceptable - Minor problems encountered with the insert. Task accomplished with some difficulty. Some degradation of mission/task accomplishment or accuracy.

Mostly Unacceptable - Major problems encountered with the insert. Task accomplished with great difficulty or accomplished poorly. Significant degradation of mission/task accomplishment or accuracy.

Completely Unacceptable - The insert is unusable or unsafe. Mission/task not accomplished due to equipment deficiencies or procedural limitations.

Last four digits of SSN: _____

Number of sorties flown
with mask insert: _____1. Rate the **SEAL** provided by your mask **WITH** the insert:

1	2	3	4	5	6
Completely Acceptable	Mostly Acceptable	Somewhat Acceptable	Somewhat Unacceptable	Mostly Unacceptable	Completely Unacceptable

Problem Areas:

- _____ Leaks at high Gs
- _____ Leaks at negative Gs
- _____ Leaks at high altitudes
- _____ Leaks at low altitudes
- _____ Leaks all the time
- _____ Interferes with effective valsalva maneuver
- _____ Other (specify, in comment area)

Comment:

2. Rate the **COMFORT** of your mask **WITH** the insert:

1	2	3	4	5	6
Completely Acceptable	Mostly Acceptable	Somewhat Acceptable	Somewhat Unacceptable	Mostly Unacceptable	Completely Unacceptable

Problem Areas:

- ☐ Has to be tightened to a point that is uncomfortable
- ☐ Interferes with eyeglasses
- ☐ Causes irritation
- ☐ Causes the mask to sag
- ☐ Uncomfortable at higher altitudes
- ☐ Uncomfortable at high Gs
- ☐ Uncomfortable at negative Gs
- ☐ Uncomfortable during combat maneuvers
- ☐ Uncomfortable for lengthy use (specify approximate length)
- ☐ Uncomfortable at all times
- ☐ Other (specify, in comment area)

Comment:

3. Rate the **COMPATIBILITY** of the MASK INSERT with existing equipment:

1	2	3	4	5	6
Completely Acceptable	Mostly Acceptable	Somewhat Acceptable	Somewhat Unacceptable	Mostly Unacceptable	Completely Unacceptable

Problem Areas:

- ☐ Interferes with vision
- ☐ Interferes with microphone use
- ☐ Interferes with mask release
- ☐ Interferes with visor
- ☐ Adversely affects pressure breathing
- ☐ Adversely affects regulator flow
- ☐ Other (specify, in comment area)

Comment:

4. Rate the performance of the MASK INSERT MATERIAL (please explain any effects in the comment area).

1	2	3	4	5	6
Completely Acceptable	Mostly Acceptable	Somewhat Acceptable	Somewhat Unacceptable	Mostly Unacceptable	Completely Unacceptable

Problem Areas:

- ☐ Affected by heat
- ☐ Affected by cold
- ☐ Affected by humidity
- ☐ Affected by oxygen
- ☐ Affected by skin contact
- ☐ Deteriorated over time
- ☐ Other (specify, in comment area)

Comment:

5. Rate the overall USE of the MASK INSERT:

1	2	3	4	5	6
Completely Acceptable	Mostly Acceptable	Somewhat Acceptable	Somewhat Unacceptable	Mostly Unacceptable	Completely Unacceptable

Problem Areas:

- ☐ Installation is difficult
- ☐ Removal is difficult
- ☐ Impacts pre-flighting of mask
- ☐ Does not stay secure while mask is hanging
- ☐ Other (specify, in comment area)

Comment:

6. Did the insert **IMPROVE THE SEAL** of your mask (Circle one)?

Yes

No

7. Did the insert **IMPROVE THE COMFORT** of your mask (Circle one)?

Yes

No

8. Would you continue to **USE THE MASK INSERT** (Circle one)?

Yes

No

9. If there is some aspect of the mask insert that has not been covered by the previous questions, provide additional comments in the following comment area.

Comment:

APPENDIX B SAMPLING MATRIX COMPUTATIONS

As stated in the body of the document, the following assumptions were used to derive the required sample size:

1. The F-16 pilot population is roughly 1,300.
2. Forty percent of F-16 pilots have problems with their mask ($1300 \times 0.40 = 520$).
3. The mask insert must improve performance and comfort for at least 75 percent of those with problems ($520 \times 0.75 = 390$).
4. Therefore, the minimum *acceptance* rate is 30 percent ($390/1300$).
5. A confidence level of 95 percent, with a 10 percent error rate is required.
6. A one-tailed test of significance is appropriate.

The required sample size (n) was derived using the following formula for a binomial distribution (the binary response being Acceptance/Rejection):

$$n = [z (\alpha/2)^2 * p * q] / E^2$$

Where:

z = Criterion statistic for the one-tailed confidence interval, $z(95 \text{ percent}) = 1.64$

E = Error rate, $E = 10$

p = acceptance rate, $p = .30$

q = $1-p$ or the rejection rate, $q = .70$

Solving for n we get 56.99. Thus, a sample size of 57 should be sufficient to confirm the null hypothesis that the insert improves mask seal/comfort. However, after data have been collected, z can be computed for the observed acceptance rate. The ratio of observed acceptance to total observations plays a critical role in computing the z statistic. Therefore, by computing this value on an on-going basis, we can reduce the required sample size *if the resulting ratio is large*. We use the following formula to compute z :

$$z = (p1 - p) / \sqrt{pq/n}$$

Where:

n = Number of observations

x = Number of acceptances

$p1 = x / n$

p = minimum acceptance rate, $p = .30$

$q = 1-p$, $q = .70$

Using this formula, we derive a value for z that is compared to the criterion statistic, $z(95 \text{ percent}) = 1.64$. If the derived value is equal to or greater than the criterion value then we can accept the null hypothesis that the insert will improve mask seal/comfort for at least 30 percent of F-16 pilots. Table B-1 illustrates values of z based on number of observations (n) and

acceptance rate (pI). As shown in the table, if 50 percent of 20 (or greater) pilots find that the mask improves seal/comfort, there is a sufficient sample size to meet the confidence level and error rate requirements.

Table B-1. Values of z based on number of observations (n) and acceptance rate

n	Acceptance Rate					
	10 percent	20 percent	30 percent	40 percent	50 percent	60 percent
20	-1.95	-0.98	0.00	0.98	1.95	2.93
30	-2.39	-1.20	0.00	1.20	2.39	3.59
40	-2.76	-1.38	0.00	1.38	2.76	4.14
50	-3.09	-1.54	0.00	1.54	3.09	4.63
57	-3.28	-1.56	0.00	1.75	3.37	4.98

**APPENDIX C
ACRONYMS**

AAOM	Advanced Aircrew Oxygen Mask
AFB	Air Force Base
AFOTEC/TA	Air Force Operational Test and Evaluation Center, Rapid Test and Assessment Directorate
ALCFT	Armstrong Laboratory Crew Technology Division
ANG	Air National Guard
DESA	Defense Evaluation Support Activity
G-forces	gravity forces
L/W	large/wide
M/N	medium/narrow
M/W	medium/wide
S/N	small/narrow
SME	subject matter expert
SSN	Social Security number
UKANG	United Kingdom Air National Guard